

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Aug 2026

Comparing the effectiveness of midwife-led integrative couple counseling with routine care on sexual desire discrepancy in couples after their delivery

Protocol summary

Study aim

Comparing the effectiveness of midwife-led integrative couple counseling with routine care on sexual desire discrepancy in couples after their delivery

Design

A randomized controlled clinical trial with two parallel intervention and control arms

Settings and conduct

Visiting health centers, urban family doctor and selected gynecologists' offices, identifying eligible people, dividing patients into two intervention and control groups randomly, completing questionnaires by both groups, evaluating results using Porsline through the network Eitaa or WhatsApp social media will be done.

Participants/Inclusion and exclusion criteria

Declaration of written consent of both couples to participate in the study/ women of childbearing age / at least 10 weeks have passed after their delivery / return of menstruation / living with a spouse / access to a smartphone (to complete the form and questionnaires in the Porsline) / availability in length of the study / No other chronic physical diseases / No addiction / No pregnancy / No mental disorders (depression, anxiety and stress based on the DASS-21 questionnaire) or physical diseases that interfere with their daily functioning/ No consumption Psychiatric drugs/ lack of participation in educational and counseling courses related to improving sexual function in the last 6 months/ lack of history of genital or pelvic surgeries (such as hysterectomy) that affect their sexual desire.

Intervention groups

Couple counseling sessions will be conducted in 5 sessions of 60 minutes at an interval of one week. Control group: In addition to routine midwifery care, after completing the study, a pamphlet containing educational materials will be provided to them during a session.

Main outcome variables

Sexual desire discrepancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161126031117N17**

Registration date: **2024-11-12, 1403/08/22**

Registration timing: **prospective**

Last update: **2024-11-12, 1403/08/22**

Update count: **0**

Registration date

2024-11-12, 1403/08/22

Registrant information

Name

Soghra Khani

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 8918

Email address

s.khani@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-21, 1403/09/01

Expected recruitment end date

2025-01-20, 1403/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of midwife-led integrative couple counseling with routine care on sexual desire discrepancy in couples after their delivery

Public title
The effectiveness of integrative couple counseling on sexual desire discrepancy after delivery

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Declaration of written consent of both couples to participate in the study Women of childbearing age At least 10 weeks have passed after their delivery Return of menstruation Living with a spouse Access to a smartphone (to complete the form and questionnaires in the Porsline) Availability in Length of the study
Exclusion criteria:
Other chronic physical diseases Addiction Pregnancy Suffering from mental disorders (depression, anxiety and stress based on the DASS-21 questionnaire) or physical diseases that interfere with their daily functioning. Consumption Psychiatric drugs Participating in educational and counseling courses related to improving sexual function in the last 6 months History of genital or pelvic surgeries (such as hysterectomy) that affect their sexual desire

Age
From **18 years** old to **54 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the samples are matched based on the duration of marriage, the number of births and breastfeeding, and the block method will be used for the random allocation of the samples. For this purpose, two blocks will be considered. Two possible blocks are TC and CT, where T is for the intervention group and C is for the control group. The numbers will be generated randomly (with the RANDBETWEEN command in Excel software and in domain 1 and 2) And according to the production values of one of the blocks (production number 1 for CT block , production number 2 for TC blocks) will be selected and samples will be allocated. The sampling method will be done in convenience method.

Blinding (investigator's opinion)
Single blinded

Blinding description
The evaluation of the consequences will be done using the PORSLINE through the social networks Eitaa or WhatsApp. The researcher and the evaluator do not know the group to which the participant belongs when evaluating the outcome.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Moalem Square, Moalem Street
City
Sari
Province
Mazandaran
Postal code
4816715793

Approval date
2024-10-01, 1403/07/10

Ethics committee reference number
IR.MAZUMS.REC.1403.304

Health conditions studied

1

Description of health condition studied
sexual desire discrepancy of couples

ICD-10 code
F52.0

ICD-10 code description
Hypoactive sexual desire disorder

Primary outcomes

1

Description
sexual desire discrepancy of couples

Timepoint
Determining the sexual desire discrepancy of couples before, immediately and 4 weeks after the intervention

Method of measurement
Using Halbert Sexual Desire Questionnaire, the sexual desire score of each couple will be calculated. The couple's desire discrepancy scores will be calculated as the difference between the couple's sexual desire scores

in the Halbert questionnaire, after standardization. That is, men's Z score from women's Z score will be reduced. For the discrepancy to be significant, the absolute value of the Z score with a 95% confidence interval should be greater than 1.96.

Secondary outcomes

1

Description

Sexual satisfaction

Timepoint

Determining the sexual satisfaction of couples before, immediately and 4 weeks after the intervention

Method of measurement

Larson's standard sexual satisfaction questionnaire

Intervention groups

1

Description

Intervention group: Counseling sessions with the presence of couples will be conducted for an average of 60 minutes and during 5 sessions with an interval of one week. People will be contacted once or twice a week to ensure that they complete their assignments. Immediately after the completion of the intervention sessions, there will be a post-test and a session to follow up and re-evaluate the two groups in terms of the couples' sexual desire discrepancy and sexual satisfaction, four weeks later.

Category

Behavior

2

Description

Control group: Control group: In addition to receiving routine midwifery care, after completing the study, they will be provided with a pamphlet containing educational materials about sexual desire discrepancy of couples and sexual satisfaction after delivery and solutions to improve it in a session.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers, urban family doctor bases

Full name of responsible person

Dr. Soghra Khani

Street address

Vesal Street, Amir Mazandarani Boulevard, Sari, Mazandaran Province,

City

sari

Province

Mazandaran

Postal code

4816715793

Phone

+98 11 3336 8918

Fax

+98 11 3336 8915

Email

khanisog343@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Ahmad Ali Enayati

Street address

Moalem square, Moalem street

City

sari

Province

Mazandaran

Postal code

4816717887

Phone

+98 11 3339 8303

Fax

+98 11 3339 8303

Email

enayati@mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh Tousheh

Position

Master's student

Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Hamzehkala Square
City
babol
Province
Mazandaran
Postal code
4731714576
Phone
+98 11 3234 1294
Email
f.tousheh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Soghra Khani
Position
PhD/ Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Vasal St, Amir Mazandarani Blvd
City
sari
Province
Mazandaran
Postal code
4816715793
Phone
+98 11 3336 8918
Fax
+98 11 3336 8915
Email
khanisog343@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Fatemeh Tousheh
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work

Midwifery
Street address
Hamzehkala Square
City
Babo;
Province
Mazandaran
Postal code
4731714576
Phone
+98 11 3234 1294
Email
f.tousheh@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The information related to the research is shared with the aim of keeping the names of the people and keeping their identities confidential and complying with the 31 code of ethics

When the data will become available and for how long

Since 1404

To whom data/document is available

All researchers and those interested in research

Under which criteria data/document could be used

To conduct review and supplementary research and for the use of Therapists and counselors of couples' sexual disorders

From where data/document is obtainable

In order to receive documents or data, the corresponding author can be reached by email at khanisog343@gmail.com and counseling student in midwifery at f.tousheh@gmail.com. If the article is published according to the journal address, you can refer to that journal.

What processes are involved for a request to access data/document

First, you should send an email to the responsible author of the article and make your request, and if the responsible author and the research team deem it appropriate, the documents and files will be provided in a short period of time.

Comments